

This invention is designed to help restrain small structural or minor fracture fragments, and the macromolecules they produce in specified compartment. The device is composed of a single sheet of material that in its principal embodiment is supplied as a thin, pliable, fabric that is flexible in three dimensions and is minimally porous to macromolecules. When the method of use contains the secondary step of affixing a treating material to the device prior to use, additional materials can be delivered directly and preferentially into specific compartments. Moreover, because the device can be made of a soft fabric, a needle can be passed through the device and additional treating materials can be repeatedly injected into and contained after the device has been deployed. The invention also permits delivery of energy directly and specifically to the treated surface. The rate of repair can be further accelerated by the attachment of a treating material, either mechanically or by chemical bond, to one surface of the device.

Claim 1 of the '760 patent is reproduced below:

A flexible fixation device for implantation into human or animal tissue to promote healing of a damaged tissue comprising:

a layer of flexible material that is minimally porous to macromolecules, said layer having a first and second major surface, the layer being capable of being shaped in three dimensions by manipulation by human hands,

the first major surface of the layer being adapted to be placed adjacent to a damaged tissue,

the second major surface of the layer being adapted to be placed opposite to the damaged tissue,

the layer having material release means for release of an at least one treating material in a directional manner when said layer is placed adjacent to a damaged tissue,

the device being flexible in three dimensions by manipulation by human hands,

the device being capable of substantially restricting the through passage of at least one type of macromolecule therethrough.

III. GENERAL PRINCIPLES GOVERNING CLAIM CONSTRUCTION

“A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention.” *Burke*,

Inc. v. Bruno Indep. Living Aids, Inc., 183 F.3d 1334, 1340 (Fed. Cir. 1999). Claim construction is an issue of law for the court to decide. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).

To ascertain the meaning of claims, the Court looks to three primary sources: the claims, the specification, and the prosecution history. *Markman*, 52 F.3d at 979. The specification must contain a written description of the invention that enables one of ordinary skill in the art to make and use the invention. *Id.* A patent's claims must be read in view of the specification, of which they are a part. *Id.* For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. *Id.* "One purpose for examining the specification is to determine if the patentee has limited the scope of the claims." *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882 (Fed. Cir. 2000).

Nonetheless, it is the function of the claims, not the specification, to set forth the limits of the patentee's invention. Otherwise, there would be no need for claims. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc). The patentee is free to be his own lexicographer, but any special definition given to a word must be clearly set forth in the specification. *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388 (Fed. Cir. 1992). Although the specification may indicate that certain embodiments are preferred, particular embodiments appearing in the specification will not be read into the claims when the claim language is broader than the embodiments. *Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994).

This Court's claim construction decision must be informed by the Federal Circuit's decision in *Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). In *Phillips*,

the court set forth several guideposts that courts should follow when construing claims. In particular, the court reiterated that “the *claims* of a patent define the invention to which the patentee is entitled the right to exclude.” 415 F.3d at 1312 (emphasis added) (*quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). To that end, the words used in a claim are generally given their ordinary and customary meaning. *Id.* The ordinary and customary meaning of a claim term “is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1313. This principle of patent law flows naturally from the recognition that inventors are usually persons who are skilled in the field of the invention and that patents are addressed to and intended to be read by others skilled in the particular art. *Id.*

The primacy of claim terms notwithstanding, *Phillips* made clear that “the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.* Although the claims themselves may provide guidance as to the meaning of particular terms, those terms are part of “a fully integrated written instrument.” *Id.* at 1315, *quoting Markman*, 52 F.3d at 978. Thus, the *Phillips* court emphasized the specification as being the primary basis for construing the claims. *Id.* at 1314-17. As the Supreme Court stated long ago, “in case of doubt or ambiguity it is proper in all cases to refer back to the descriptive portions of the specification to aid in solving the doubt or in ascertaining the true intent and meaning of the language employed in the claims.” *Bates v. Coe*, 98 U.S. 31, 38 (1878). In addressing the role of the specification, the *Phillips* court quoted with approval its earlier

observations from *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998):

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

Phillips, 415 F.3d at 1316. Consequently, *Phillips* emphasized the important role the specification plays in the claim construction process.

The prosecution history also continues to play an important role in claim interpretation. Like the specification, the prosecution history helps to demonstrate how the inventor and the PTO understood the patent. *Id.* at 1317. Because the file history, however, “represents an ongoing negotiation between the PTO and the applicant,” it may lack the clarity of the specification and thus be less useful in claim construction proceedings. *Id.* Nevertheless, the prosecution history is intrinsic evidence that is relevant to the determination of how the inventor understood the invention and whether the inventor limited the invention during prosecution by narrowing the scope of the claims. *Id.*

Phillips rejected any claim construction approach that sacrificed the intrinsic record in favor of extrinsic evidence, such as dictionary definitions or expert testimony. The *en banc* court condemned the suggestion made by *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed. Cir. 2002), that a court should discern the ordinary meaning of the claim terms (through dictionaries or otherwise) before resorting to the specification for certain limited purposes. *Phillips*, 415 F.3d at 1319-24. The approach suggested by *Texas Digital*—the assignment of a limited role to the specification—was rejected as inconsistent with decisions holding the

specification to be the best guide to the meaning of a disputed term. *Id.* at 1320-21. According to *Phillips*, reliance on dictionary definitions at the expense of the specification had the effect of “focus[ing] the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent.” *Id.* at 1321. *Phillips* emphasized that the patent system is based on the proposition that the claims cover only the invented subject matter. *Id.* What is described in the claims flows from the statutory requirement imposed on the patentee to describe and particularly claim what he or she has invented. *Id.* The definitions found in dictionaries, however, often flow from the editors’ objective of assembling all of the possible definitions for a word. *Id.* at 1321-22.

Phillips does not preclude all uses of dictionaries in claim construction proceedings. Instead, the court assigned dictionaries a role subordinate to the intrinsic record. In doing so, the court emphasized that claim construction issues are not resolved by any magic formula. The court did not impose any particular sequence of steps for a court to follow when it considers disputed claim language. *Id.* at 1323-25. Rather, *Phillips* held that a court must attach the appropriate weight to the intrinsic sources offered in support of a proposed claim construction, bearing in mind the general rule that the claims measure the scope of the patent grant.

The patent-in-suit includes claim limitations that are argued to fall within the scope of 35 U.S.C. § 112, ¶ 6. “An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure. . . in support thereof, and such claim shall be construed to cover the corresponding structure . . . described in the specification and equivalents thereof.” 35 U.S.C. § 112, ¶ 6. When a claim uses the term “means” to describe a limitation, a presumption inheres that the inventor used the term to invoke

§ 112, ¶ 6. *Biomedino, LLC v. Waters Technologies Corp.*, 490 F.3d 946, 950 (Fed. Cir. 2007). “This presumption can be rebutted when the claim, in addition to the functional language, recites structure sufficient to perform the claimed function in its entirety.” *Id.*, citing *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1375 (Fed. Cir. 2003). By contrast, when a claim term does not use “means,” the term is presumptively not subject to § 112, ¶ 6. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1369 (Fed. Cir. 2002); *MIT v. Abacus Software*, 462 F.3d 1344, 1353 (Fed. Cir. 2006). A limitation lacking the term “means” may overcome the presumption if it is shown that “the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function.” *MIT*, 462 F.3d at 1353, quoting *CCS Fitness*, 288 F.3d. at 1369. “What is important is whether the term is one that is understood to describe structure, as opposed to a term that is simply a nonce word or a verbal construct that is not recognized as the name of structure and is simply a substitute for the term ‘means for.’” *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1360 (Fed. Cir. 2004).

Once the court has concluded the claim limitation is a means-plus-function limitation, the first step in construing a means-plus-function limitation is to identify the recited function. *See Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999). The second step in the analysis is to identify in the specification the structure corresponding to the recited function. *Id.* The “structure disclosed in the specification is ‘corresponding’ structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.” *Medical Instrumentation and Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 (Fed. Cir. 2003), citing *B. Braun v. Abbott Labs*, 124 F.3d 1419, 1424 (Fed. Cir.

1997). The patentee must clearly link or associate structure with the claimed function as part of the quid pro quo for allowing the patentee to express the claim in terms of function pursuant to § 112, ¶ 6. *See id.* at 1211; *see also Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1377 (Fed. Cir. 2001). The “price that must be paid” for use of means-plus-function claim language is the limitation of the claim to the means specified in the written description and equivalents thereof. *See O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1583 (Fed. Cir. 1997). “If the specification does not contain an adequate disclosure of the structure that corresponds to the claimed function, the patentee will have ‘failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112,’ which renders the claim invalid for indefiniteness.” *Blackboard, Inc. v. Desire2Learn, Inc.*, 574 F.3d 1371, 1382 (Fed. Cir. 2009), *quoting In re Donaldson Co.*, 16 F.3d 1189, 1195 (Fed. Cir. 1994) (en banc). It is important to determine whether one of skill in the art would understand the specification itself to disclose the structure, not simply whether that person would be capable of implementing the structure. *See Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1382 (Fed. Cir. 1999); *Biomedino*, 490 F.3d at 953. Fundamentally, it is improper to look to the knowledge of one skilled in the art separate and apart from the disclosure of the patent. *See Medical Instrumentation*, 344 F.3d at 1211-12. “[A] challenge to a claim containing a means-plus-function limitation as lacking structural support requires a finding, by clear and convincing evidence, that the specification lacks disclosure of structure sufficient to be understood by one skilled in the art as being adequate to perform the recited function.” *Budde*, 250 F.3d at 1376-77.

IV. AGREED CONSTRUCTIONS

Based upon the joint submission of claim construction charts, the following terms of the

patent have been agreed to by the parties, and therefore adopted by the Court:

Claim Term/Phrase	Agreed Construction
<i>“damaged tissue”</i>	“tissue that has been injured by trauma as well as tissue that is abnormal because of disease, infection, or other soft tissue metastases”
<i>“macromolecules”</i>	“molecules with a molecular weight of at least approximately 500 Daltons”
<i>“small molecules”</i>	“molecules having a size on the order of water, bicarbonate, urea, and hydrogen ions”

V. TERMS IN DISPUTE OF THE ‘760 PATENT

1. “device”

Claim Term/Phrase	Plaintiff’s Proposed Construction	Defendants’ Proposed Construction
<i>“device”</i>	“at least the layer recited previously in the respective claims”	“a single sheet of material”

The Court concludes that because the preamble is not limiting in the context of this claim, “device” refers to “a device having the limitations called out by the body of the claim.” The present claim construction dispute is not the first opportunity for this Court to construe the ‘760 patent. In a prior case, the Court was asked to construe the term “device” as a “sheet.” *Saffran v. Boston Scientific Corp.*, No. 2:05-CV-547 (TJW), 2008 WL 2716318, at *6 (E.D. Tex. July 9, 2008). The Court refused then, and for the reasons below, the Court again refuses.

A. Parties’ Construction Arguments

Defendants seek a construction of “device” as “a single sheet of material.” Defendants argue the specification limits “device” to a single sheet of material and the prosecution history shows repeated disclaimers. Defendants note several places in the specification where the

“device” is referred to as a “sheet.” For example, Defendants point out that the specification in one place unequivocally states “the device, 1, is composed of a single sheet of material.” 13:38-40. In addition, Defendants argue there are no embodiments other than a single sheet of material. Even though Plaintiff claims, for example, in Figure 6(a) the “device” is a “spray” and not a “sheet,” Defendants argue that even the “spray” embodiment creates a “sheet”—the “sheet” is sprayed on. *See* Fig. 6(a). Regarding the prosecution history, Defendants point out that Plaintiff, when arguing around the prior art by Gaskill, stated his “device is a sheet rather than a pre-formed chamber.” Applicant’s 9/13/96 Response to Examiner’s 6/12/96 Office Action, at 5, attached as Ex. 13 to Defendants’ Amended Answering Brief, Dkt. No. 102. Defendants argue this is a disclaimer in prosecution.

Plaintiff argues that “device” should not be construed as a “single sheet of material” because there is no clear intention to limit the claim scope to a “sheet” in the specification. Instead, Plaintiff argues the specification shows that a “sheet” is merely a preferred embodiment of the “device.” Plaintiff argues there are also other embodiments of the “device” disclosed in the specification such as “spray” or “coating” embodiments. *See, e.g.*, 18:30-33 (“the invention can be applied to the site of injury as a spray”). Therefore, “device” cannot be limited to “sheet” because then it could not encompass the “spray” or “coating” embodiments discussed in the specification. Although there is language in the prosecution history potentially limiting “device” to “sheet,” Plaintiff argues these citations are made merely to distinguish the prior art. For example, the patentee stated “[t]he device is a sheet rather than a pre-formed chamber (Gaskill).” Applicant’s 9/13/96 Response to Examiner’s 6/12/96 Office Action, at 5, attached as Ex. 13 to Defendants’ Amended Answering Brief, Dkt. No. 102. Plaintiff argues these statements are not

words of manifest exclusion or restriction to a “sheet”; instead, these statements exclude a pre-formed chamber like Gaskill’s.

Plaintiff asks the Court to construe “device” as “at least the layer recited previously in the respective claims.” Plaintiff argues that “device” should have its ordinary meaning and that “device” takes on its ordinary meaning by “simply pointing to the preferred embodiments disclosed in the specification.” (Dkt. No. 97. at 21.) Plaintiff’s rationale for its construction is not clear in its briefing, but at the hearing Plaintiff clarified that Plaintiff’s proposed construction for “device” is related to the “comprising” language used in claim 1. Plaintiff argues that given the open-ended “comprising” language in claim 1, the inventor has claimed “at least” the layer recited in the claim language.

B. Analysis

The Court refuses to read in Defendants’ “sheet” limitation for the term “device.” The Court will first consider the intrinsic evidence. Defendants point out that the specification refers to the “device” as a “sheet” in multiple places. *See, e.g.*, 12:21-22 (“[s]ingle layered, flexible, minimally porous sheet having macromolecular restraintment means”); 13:38-40 (“the device, 1, is composed of a single sheet of material”). Nevertheless, the Court agrees with Plaintiff that a “sheet” is merely a preferred embodiment of the “device.” The specification states that the “sheet” is the “principal embodiment” or merely “one embodiment” of the “device.” 7:57-60; 13:39-41. Defendants’ references to the specification where it states, for example, that the device is composed of a single sheet of material are not enough to give rise to a “clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting *Teleflex* at

1327). The Federal Circuit has cautioned that “limitations appearing in the specification will not be read into claims, and . . . interpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.” *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1348 (Fed. Cir. 2002) (citing *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989)) (internal quotes omitted). In Defendants’ proposed claim construction, they seek to do what the Federal Circuit has cautioned against by adding the “sheet” limitation into the claim language. By reading in the “sheet” limitation proposed by Defendants, the Court would be ignoring the “spray” and “coating” embodiments disclosed by the patentee. “We normally do not interpret claim terms in a way that excludes disclosed examples in the specification.” *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007). The specification gives several examples of other embodiments of the “device” besides a “sheet,” such as a “coating” and a “spray.” *See, e.g.*, 6:49-50 (“The invention is to be provided as a flexible sheet, spray or tube”); 7:11-13 (“[T]he present invention . . . can be applied as a spray film.”); 12:64-65 (“Spray stream that forms the invention when the spray hits a solid surface.”); 21:8-9 (“this invention being used to coat a stent”). Hence, the Court refuses to construe the “device” as a “sheet” because it would exclude the patentee’s disclosure of other embodiments such as the spray, tube, or coating.

The Court also rejects Defendants’ prosecution disclaimer argument. To be a disclaimer, the statement in prosecution history must be clear and unambiguous and constitute a clear disavowal of the scope. *Verizon*, 503 F.3d at 1306. In addition, the prosecution history is often less informative than the specification. *Phillips*, 415 F.3d at 1315. The patentee stated in prosecution, for example, that “[t]he device is a sheet rather than a pre-formed chamber

(Gaskill).” Applicant’s 9/13/96 Response to Examiner’s 6/12/96 Office Action, at 5, attached as Ex. 13 to Defendants’ Amended Answering Brief, Dkt. No. 102. While the patentee may have clearly disavowed a pre-formed chamber, the patentee did not clearly disavow every possible embodiment besides a sheet. The disclaimer must be unambiguous, and the only unambiguous disclaimer here was the pre-formed chamber. The specification as discussed above shows other embodiments besides a sheet, and the specification speaks with more clarity than the prosecution history in claim construction. Therefore, the Court rejects Defendants’ prosecution disclaimer argument.

The Court additionally rejects Plaintiff’s construction of “device” as “at least the layer recited previously in the respective claims.” The Court is not persuaded by Plaintiff’s argument that this language is necessary to reflect the “comprising” language in the claims. The term “comprising,” as used in claim 1 and other independent claims in the patent-in-suit, is a transitional term in patent law that is inclusive or open-ended and does not exclude additional elements or steps. *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1235 (Fed. Cir. 2005). Of course, as a patent law term of art, the “comprising” term will be given its customary meaning, but this Court need not construe “device” to reflect the open-ended nature of the “comprising” language because such a construction would be redundant and unnecessary given the “comprising” language already in the claim.

In all, the Court concludes that because the preamble is not limiting in the context of this claim, “device” refers to “a device having the limitations called out by the body of the claim.” The term “device” is in the preamble of claim 1. *See* Claim 1, 22:29-31 (“1. A flexible fixation device . . . comprising: . . .”). After the preamble, “device” is referenced on an antecedent basis

in the body of claim 1; therefore, at all times in claim 1 the term “device” is referring to the “device” introduced in the preamble. *See* Claim 1, 22:29-43 (“1. A flexible fixation device . . . comprising: . . . the device being flexible in three dimensions by manipulation by human hands, the device being capable of substantially restricting the through passage of at least one type of macromolecule therethrough.”). Further, in other claims, the term “device” is either referring to the “device” in claim 1 or a method for using such a device in claims 8 through 18.

The Federal Circuit’s opinion in *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422 (Fed. Cir. 2000) is instructive. There the court was reviewing a construction of the phrase “control apparatus” in the preamble of the patent-in-suit. *Id.* The particular claim, which was claim 1, read as “[a] programmable microcomputer control apparatus for controlling the relative motion between a tool and a workpiece comprising:” *Id.* at 1427. The court determined that the preamble was not a claim limitation and was irrelevant to the proper construction of the claim. *Id.* at 1434. The court stated that “[t]he phrase ‘control apparatus’ in the preamble merely gives a descriptive name to the set of limitations in the body of the claim that completely set forth the invention . . . [so] [t]he claim is infringed by any apparatus encompassing all of the limitations in the body of the claim.” *Id.*

The reasoning from *IMS Tech.* applies here. As in *IMS Tech.*, the phrase “device” used in the preamble merely gives a descriptive name to the set of limitations in the body of the claim that set forth the invention. Later references to “device” in claim 1 or other claims either refer to the “device” in the preamble on an antecedent basis or are referring to a method of using that device. To put it another way, in claim 1, which is a machine or apparatus claim, the inventor uses the label “device” to refer to the machine or apparatus that contains the set of limitations set

forth in the body of the claim. Therefore, “device” refers to “a device having the limitations called out by the body of the claim.”

2. “a layer of flexible material that is minimally porous to macromolecules”

Claim Term/Phrase	Plaintiff’s Proposed Construction	Defendants’ Proposed Construction
<i>“layer”</i>	No construction is required. But if the phrase does require construction, then it should be construed to mean “any thickness of material,” with no other physical or structural restrictions aside from those otherwise recited in the claims associated with the term.	“a single layer (one and only one layer)”
<i>“that is minimally porous to macromolecules”</i>	“that is capable of substantially containing macromolecules on one side of the material” Plaintiff also argues that the phrase “minimally porous to macromolecules” modifies the term material and not the term layer.	“that is substantially impermeable to macromolecules” In addition, this phrase (the entire phrase including “layer” and “minimally porous”) does not encompass a layer on a stent that leaves uncovered mesh holes which allow macromolecules to freely move through them. Defendants also argue that the phrase “minimally porous to macromolecules” modifies the term layer.

The Court construes the term “layer” as “a single layer.” For the phrase “that is minimally porous to macromolecules,” the Court agrees with Defendants and construes the phrase as “that is substantially impermeable to macromolecules.” However, the Court disagrees with Defendants that the phrase “minimally porous to macromolecules” modifies the term “layer”; instead, the Court concludes that the phrase “minimally porous to macromolecules” modifies the term “material.”

A. Parties’ Construction Arguments

For the term “layer,” Plaintiff argues the term has a plain meaning and is readily understandable so it requires no construction. In the alternative, Plaintiff argues the Court should construe the term to mean “any thickness of material” (with no other physical or structural limitations than those otherwise in the claims). In support, Plaintiff’s argument is the extrinsic evidence supports such a construction. Plaintiff relies on a dictionary definition that defines “layer” as a “thickness of material covering a surface or forming an overlaying part or segment.” *See The American Heritage Dictionary of the English Language* 1022 (3rd ed. 1992). Plaintiff argues the Court should not adopt Defendants’ construction that reads “a single layer (one and only one layer).” Plaintiff’s reasoning is that the claim uses the open-ended “comprising” language, so the Court should not construe the claim to prohibit the addition of features or structures beyond those recited in the claim.

Regarding the phrase “that is minimally porous to macromolecules,” Plaintiff argues the specification provides clear guidance for the meaning of the phrase. The specification states that the material of the layer is “minimally porous as described above such that it is capable of substantially containing macromolecules on one side of the device.” 15:56-58. Plaintiff argues this supports a construction of “capable of substantially containing macromolecules on one side of the material.” Plaintiff also argues the language “minimally porous to macromolecules” modifies the term “material” in the phrase “a layer of flexible material that is minimally porous to macromolecules.” 22:33-34.

Defendants seek a construction of “layer” that reads “a single layer (one and only one layer).” Defendants primarily rely on multiple representations in the specification and prosecution history where the term “layer” is stated to be a single layer and is distinguished from

other two layer devices. For the phrase “minimally porous to macromolecules,” Defendants seek a construction of “substantially impermeable to macromolecules.”¹ Defendants cite the specification where it states “[t]he device itself must be substantially impermeable to macromolecules.” 13:42-43. However, the major disagreement regarding the phrase “minimally porous to macromolecules” is whether it modifies the term “layer” or “material.” Defendants argue the phrase modifies the term “layer.”

B. Analysis

The Court construes the term “layer” as “a single layer.” The intrinsic record supports a conclusion that the inventor has limited the layer to a single layer. As the Federal Circuit stated in *Phillips*, 415 F.3d at 1316, “[i]n [some] cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance . . . , the inventor has dictated the correct claim scope, and the inventor’s intention, as expressed in the specification, is regarded as dispositive.” Further, “[t]he patentee is held to what he declares during the prosecution of his patent.” *Gillespie v. Dywidag Sys. Int’l*, 501 F.3d 1285, 1291 (Fed. Cir. 2007). In the specification of the patent-in-suit, the inventor clearly limited the scope of the term layer to a single layer. The specification states multiple times that the “present invention” is “single-layered.” *See, e.g.*, 6:26-27 (“The present invention is provided as a single-layered malleable fixation device”). Additionally, the inventor had a previous invention, and consequently prior art for the patent-in-suit, that consisted of two layers. *See* U.S. Patent No.

¹ Note that in Defendants’ brief they incorporate the agreed upon construction of “macromolecules” in their construction of the present phrase by stating “substantially impermeable to molecules with a molecular weight of at least approximately 500 Daltons” instead of “substantially impermeable to macromolecules.” The Court has removed the incorporation of the construction for “macromolecules” for the reason of brevity here.

5,466,262 (filed Aug. 30, 1993). In the specification of the patent-in-suit, Plaintiff stated the invention of the patent-in-suit “is a single, thin layer of material as opposed to the structure of the Malleable Fracture Stabilization Device with Micropores for Directed Drug Delivery [the ‘262 patent] shown in FIG. 1b [which clearly shows two layers].” 13:58-63. Indeed, the inventor notes that eliminating one of the layers on the older two-layer device, and thus making it a single layer, is advantageous:

Because a fundamental tenant of surgical practice to [sic] keep the amount of foreign material placed within the body to an absolute minimum, any decrease in the amount of implant used is of benefit to the patient. Therefore, the elimination of an entire layer while maintaining function is a highly significant improvement in design.

7:47-52. Thus, the inventor limited the scope of the term layer to a single layer in the specification by expressly limiting the invention to a single layer and distinguishing prior art on the basis of the single layer. In addition, the inventor limited the layer to a single layer during the prosecution of the patent. The inventor distinguished the invention in the patent-in-suit from the prior art because it was “a single layer rather than two layers.” *See, e.g.*, Applicant’s 9/13/96 Response to Examiner’s 6/12/96 Office Action, at 5, attached as Ex. 13 to Defendants’ Amended Answering Brief, Dkt. No. 102. Based on its review of the intrinsic record, the Court concludes that the inventor disclaimed the scope of “layer” to a single layer, and so the Court construes the term “layer” as “a single layer.”

The Court rejects Plaintiff’s argument that the Court should not construe “layer” as “a single layer” because the claims, such as claim 1, use the open-ended “comprising” language. As discussed above with the claim term “device,” the term “comprising” is a transitional term in patent law that is inclusive or open-ended and does not exclude additional elements or steps.

CollegeNet, 418 F.3d at 1235. As with “device,” the Court need not construe “layer” in a way to reflect the open-ended nature of the “comprising” language. Of course, Plaintiff will be able to take advantage of the “comprising” language when proving infringement of those claims including that transitional phrase. However, the Federal Circuit has warned that while “a transitional term such as ‘comprising’ . . . does not exclude additional unrecited elements . . . , ‘[c]omprising’ is not a weasel word with which to abrogate claim limitations.” *Spectrum Int’l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1379-80 (Fed. Cir. 1998) (internal quotes omitted); *see also Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007). Hence, Plaintiff may not use the “comprising” language for the purpose of getting around the disclaimer that the “layer” is “a single layer,” and thus disregarding the Court’s construction of “layer.”

For the phrase “that is minimally porous to macromolecules,” the Court agrees with Defendants’ proposed construction reading “that is substantially impermeable to macromolecules.” The intrinsic record supports this construction. The specification specifically states that the device must be “substantially impermeable to macromolecules.” 13:43-44. Further, such a construction comports with the ordinary and customary meaning of the phrase “minimally porous to macromolecules.”² The Court disagrees with Plaintiff’s proposed construction that reads “capable of substantially containing macromolecules on one side of the material.” Plaintiff’s citation to the specification is misleading because the specification reads “one side of the device” and not “one side of the material” as Plaintiff proposes. *See* 15:56-58.

² Since the word “porous” means the opposite of “impermeable,” if something is “minimally porous” it can be said to be “substantially impermeable.” *Compare Merriam-Webster’s Collegiate Dictionary* 966 (11th ed., Merriam-Webster, Inc. 2006) (defining “porous” as “permeable to fluids” or “capable of being penetrated”); *id.* at 624 (defining “impermeable” as “not permitting passage (as of a fluid) though its substance”).

Also, Plaintiff's construction adds ambiguity to the phrase by inserting the words "on one side" of the material. By stating "on one side" it implies that the macromolecules may be contained on either side of the material; however, the specification teaches that the macromolecules are to be preferentially contained on the specific side that is adjacent to the interfragmentary space. *See* 13:22-25 ("This invention is designed to keep . . . the macromolecules . . . in the space between the fracture fragments, i.e., the interfragmentary space . . ."). Therefore, the Court construes the phrase "that is minimally porous to macromolecules" as "that is substantially impermeable to macromolecules."

The Court agrees with Plaintiff that the language "that is minimally porous to macromolecules" modifies the term "material" and not "layer" in the claim phrase "a layer of flexible material that is minimally porous to macromolecules." 22:33-34. As Plaintiff points out, the specification states "[t]he only requirements are that the *material* be . . . 3) minimally porous as described above" 15:50-58 (emphasis added). A plain reading of the claim language in claim 1 also supports an interpretation where the phrase modifies the word "material" and not "layer." The specific phrase in claim 1 reads "*a layer of flexible material that is minimally porous to macromolecules, said layer having a first and second major surface, the layer being capable of being shaped in three dimensions by manipulation by human hands . . .*" 22:33-35 (emphasis added). Under a plain reading of the phrase, when the language is referring to the layer, it says "said layer" or "the layer." But there is no qualifying language such as "the layer" before the phrase "that is minimally porous to macromolecules." If the patentee wanted the phrase to modify the layer, then the patentee could have written "a layer of flexible material[, *the layer being*] minimally porous to macromolecules" as the patentee did in the latter part of the

phrase, yet the patentee did not include such language. *See* 22:33-34. So the Court concludes that the phrase modifies the word “material” and not “layer.”

Finally, Defendants also seek the Court to clarify that “a layer of flexible material that is minimally porous to macromolecules” does not encompass a layer on a stent that leaves uncovered mesh holes which allow macromolecules to freely move through them. The Court refuses to do so. Defendants’ issue regarding a stent that leaves uncovered mesh holes is discussed at length in the Court’s discussion below of the disputed phrase “the device being capable of substantially restricting the through passage of at least one type of macromolecule therethrough.”

3. “the layer having material release means for release of at least one treating material in a directional manner when said layer is placed adjacent to a damaged tissue”

Claim Term/Phrase	Plaintiff’s Proposed Construction	Defendants’ Proposed Construction
<p>1. A flexible fixation device for implantation into human or animal tissue to promote healing of damaged tissue comprising: . . . <i>the layer having material release means for release of at least one treating material in a directional [or unidirectional] manner when said layer is placed adjacent to a damaged tissue</i></p>	<p>The words “layer having” and “when said layer is placed adjacent to a damaged tissue” do not require construction.</p> <p>If the phrase “placed adjacent to damaged tissue” requires construction, the phrase means “placed near or in contact with damaged tissue.”</p> <p>The remainder of the clause (“material release means for release of an at least one treating material in a directional [or unidirectional] manner”) should be construed pursuant to 35 U.S.C. § 112(6).</p> <p><i>Function:</i> “to release a drug preferentially toward the damaged tissue [when the layer is placed adjacent to damaged tissue]”</p> <p><i>Corresponding Structure:</i> “chemical bonds and linkages”</p>	<p>The phrase is governed by 35 U.S.C. §112(6).</p> <p><i>Function:</i> “releasing the treating material solely in the direction of the damaged tissue when the layer is placed adjacent to a damaged tissue”</p> <p><i>Corresponding Structure:</i> <i>Structure for release:</i> “chemical bonds and linkages hydrolyzable by water and/or enzymes”</p> <p><i>Structure for directionality:</i> “a layer that is substantially impermeable to the treating material and has the treating material affixed only to the surface of the layer adjacent to the damaged tissue.”</p>

The Court agrees with Plaintiff that the beginning of the phrase (“the layer having”) and the end of the phrase (“when said layer is placed adjacent to a damaged tissue”) do not require construction.³ The Court concludes that the phrase “means for release of at least one treating

³ It is not even clear the extent Defendants dispute these portions of the phrase from Defendants’ briefing or oral argument. Further, Defendants’ proposed construction includes a function that

material in a directional [or unidirectional] manner” is governed by 35 U.S.C. §112 ¶ 6. The Court also concludes that the function of this means-plus-function claim is “to release a drug preferentially toward the damaged tissue.” The Court concludes the corresponding structure is “chemical bonds and linkages.”

The relevant claim language appears in claims 1, 8, and 15. There is a slight difference, however, in the language between the phrase in claim 1 and that in claims 8 and 15. Claim 1 says a “directional manner” and claims 8 and 15 say “unidirectional manner.” 22:41-43; 23:26-29; 24:23-25. But the parties agree that the differing language of “directional” and “unidirectional” should not affect the construction of the phrases, and the Court agrees.

A. Parties’ Construction Arguments

Regarding the function of the means-plus-function phrase, the parties have a minor dispute. Plaintiff argues the function is “to release a drug preferentially toward the damaged tissue [when the layer is placed adjacent to damaged tissue].” Defendants argue the function should be “releasing the treating material solely in the direction of the damaged tissue when the layer is placed adjacent to a damaged tissue.” The main dispute, therefore, is whether the Court should use the language “preferentially” or “solely” in the function. Plaintiff argues the specification states multiple times that the release should be “preferentially” towards the damaged tissue. Defendants argue that the Court should include “solely” because the inventor disclaimed “multidirectional” delivery in the prosecution history in order to distinguish a

uses the language “when the layer is placed adjacent to a damaged tissue,” which is nearly the same language that Plaintiff argues does not need construction. In any event, the Court will not construe the language “the layer having” and “when said layer is placed adjacent to a damaged tissue” because the Court finds these words are not part of the “material release means” means-plus-function. Further, this specific language is not complicated and would be easily understood by the jury given that the Court has already construed the term “layer” above.

reference in the prior art. Defendants also argue that this Court implied the release direction must be “solely” in the direction of the damaged tissue in the Court’s claim construction for this same patent in a prior case. *Saffran v. Boston Scientific Corp.*, No. 2:05-CV-547 (TJW), 2007 WL 2901166, at *5 (E.D. Tex. Sept. 28, 2007).

The corresponding structure of the means-plus-function results in a more significant dispute. Plaintiff argues the structure is “chemical bonds and linkages.” Plaintiff’s support is primarily in the specification, where it states, for example, the “specificity of medicine release provided by the chemical bond is entirely new and unexpected.” 15:12-17. Defendants argue there is both a release structure and a directionality structure. Defendants argue the release structure is “chemical bonds and linkages hydrolyzable by water and/or enzymes.” This construction is the same as Plaintiff’s construction except that it adds the limitation that the bonds be “hydrolyzable by water and/or enzymes.” Defendants argue that by making the structure of the function merely “chemical bonds and linkages,” the Court is focusing on the incorrect function, that is, the function is the “release,” not the “bond.” Defendants’ argument rests primarily on the specification because the specification discusses hydrolyzable bonds many times when the specification is mentioning chemical bonds. *See, e.g.*, 14:67-15:2 (“linkages can be made of any suitable bond, e.g., a bond that requires a particular enzyme for hydrolysis”). Hence, Defendants argue the only structure clearly linked to the function is the chemical bonds hydrolyzable by water. Defendants argue a directionality structure is also needed because the function performs not only a release means but also a direction means. Defendants argue this structure should be “a layer that is substantially impermeable to the treating material and has the treating material affixed only to the surface of the layer adjacent to the damaged tissue.”

Defendants argue the directionality function is necessary for the invention to perform the claimed function of release in the direction of the damaged tissue.

B. Analysis

As stated above, the Court concludes that the phrase “means for release of at least one treating material in a direction [or unidirectional] manner” is governed by 35 U.S.C. §112(6). The first step in construing a means-plus-function limitation is to identify the recited function. *Micro Chem.*, 194 F.3d at 1258. The only major dispute between the parties regarding the function is whether the treating material is released “solely” or “preferentially” in the direction of the damaged tissue. The Court agrees with Plaintiff that the treating material is released “preferentially” in the direction of the damaged tissue. The specification states multiple times that the drug is released “preferentially” towards the damaged tissue. *See, e.g.*, 1:24-26 (“a treating material . . . can be directed preferentially to the site of injury”); 6:47-49 (“both the endogenous and exogenous growth factors continue to be directed preferentially into the interfragmentary space”); 7:23-24 (“preferentially direct endogenous macromolecules”); 9:22-23 (“medicine can be applied directly and preferentially to an injured wall”). Defendants’ proposed requirement that the treating material be released “solely” in the direction of the damaged tissue is too limiting and not supported in the specification like the “preferentially” language. The word “solely” implies that the drug must be completely and only (i.e., 100%) directed towards the damaged tissue. The specification does not support this strict limitation; instead, the specification uses the language “preferentially.” Indeed, Defendant Cordis Corporation’s own witness notes that “[i]n the word of biology, there are no absolutes.” (Email from Robert Falotico to Marty Schildhouse, attached as Ex. 4 to Plaintiff’s Opening Claim Construction

Brief, Dkt. No. 97.) Although Defendants argue that the inventor disclaimed “multidirectional” release in prosecution history to get around the Scott reference, this does not necessitate that the release be “solely” in a particular direction. *See* Applicant’s 9/13/96 Response to Examiner’s 6/12/96 Office Action, at 5, attached as Ex. 13 to Defendants’ Amended Answering Brief, Dkt. No. 102. The release mechanism can be merely preferentially directed in one direction and thus not be considered multidirectional. Therefore, the function is “to release a drug preferentially toward the damaged tissue.”⁴

The second step in the analysis of a means-plus-function is to identify in the specification the structure corresponding to the recited function. *Micro Chem.*, 194 F.3d at 1258. The Court agrees with Plaintiff that the structure is “chemical bonds and linkages.” The “structure disclosed in the specification is ‘corresponding’ structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.” *Medical Instrumentation*, 344 F.3d at 1210. The specification clearly links the structure of “chemical bonds and linkages” to the function of releasing the drug preferentially toward the damaged tissue by explicitly discussing the “medicine release provided by the chemical bond.” 15:15-16. *See also* 10:10-13 (“In this example, medicine is attached to the invention using a hydrolyzable chemical bond.”); 12:55 & Fig. 3a (showing the “chemical bond” holding the treating material to the layer in Figure 3a); 14:64-65 (“Release rates can be adjusted simply by varying the linkage between the medicine and the device.”); 14:67-15:2 (“[T]he linkages can be made of any suitable bond, e.g., a bond that requires a particular enzyme for hydrolysis”).

⁴ As stated above, the Court is not construing the language “when said layer is placed adjacent to a damaged tissue,” so the Court is not including the last portion of either Plaintiff’s or Defendants’ proposed construction that merely recites that language.

Defendants argue instead that the structure clearly linked is more specifically “chemical bonds and linkages hydrolyzable by water and/or enzymes.” Defendants state that the specification refers specifically to hydrolyzable chemical bonds for the material releasing function. *See, e.g.*, 14:60-61 (“medicine is attached using a hydrolyzable bond”); 14:65-66 (“In the preferred embodiment, these linkages are hydrolyzable by the water within the interfragmentary space; however the linkages can be made of any suitable bond, e.g., a bond that requires a particular enzyme for hydrolysis.”).

Wenger Mfg., Inc. v. Coating Machinery Sys., Inc., 239 F.3d 1225 (Fed. Cir. 2001) is instructive. In *Wenger*, the Federal Circuit reviewed the construction of the means-plus-function phrase “air circulation means.” The parties disputed the structure with the plaintiff arguing that the district court erred by interpreting the “air circulation means” limitation as requiring a structure capable of recirculating air. *Id.* at 1231-32. The Federal Circuit agreed with the plaintiff stating that “the [district] court improperly restricted the ‘air circulation means’ limitation to structure that was disclosed in the preferred embodiment, but was not necessary to perform the recited function of circulating air.” *Id.* Additionally, the Federal Circuit addressed a claim differentiation argument noting “while claim 1 recites the function of ‘circulating’ air through the reel, dependent claim 3 expressly recites the additional limitation of ‘means for exhausting a first portion of said air received in said plenum and *recirculating* a second portion of said air back into the interior of said reel.’” *Id.* (emphasis in original) (internal cites omitted). The doctrine of claim differentiation states that each claim in a patent is presumptively different in scope. *Comark Commc’ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998). The court acknowledged that the Federal Circuit in *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533,

1538 (Fed. Cir. 1991) held the doctrine of claim differentiation may apply differently with respect to means-plus-function claims—stating “the judicially developed guide to claim interpretation known as ‘claim differentiation’ cannot override [§ 112, ¶ 6].” But the court in *Wenger* stated that “it does not necessarily follow that means-plus-function limitations must be interpreted without regard to other claims” and “*Laitram* does not stand for the broader proposition . . . that a means-plus-function limitation must be interpreted without regard to other claims.” *Wenger*, 239 F.3d at 1234. Hence the court concluded that “the doctrine of claim differentiation supports the conclusion that the ‘air circulation means’ limitation in claim 1 should be limited to the structure for performing the function of circulating air, and should not be interpreted as requiring structure capable of performing the additional function of recirculation, which is expressly recited in dependent claim 3 and not found in claim 1.” *Id.*

Wenger’s rationale applies here. As in *Wenger*, the structure of “chemical bonds and linkages hydrolyzable by water and/or enzymes” is merely disclosed as a preferred embodiment and is not necessary to perform the recited function of releasing a drug preferentially toward the damaged tissue. The specification specifically states that “any suitable bond” will work and, more generically, the “medicine release [is] provided by the chemical bond.” *See* 15:1-17. Further, as noted above, Figure 3a in the specification shows the medicine layer for the medicine release means, and reference numeral 24, which clearly shows the bonding on the layer, is labeled as a “chemical bond,” not a hydrolyzable chemical bond. *See* Fig. 3a; 12:55. The hydrolyzable chemical bond is, therefore, the structure for one of the embodiments disclosed in the specification.

The doctrine of claim differentiation provides further guidance that the structure cannot be limited to “chemical bonds and linkages hydrolyzable by water and/or enzymes.” The court in *Wenger* observed that while claim differentiation may not override the statutory requirements of § 112, ¶ 6, “the examination of other claims in a patent may provide guidance and context for interpreting a disputed means-plus-function limitation.” *Wenger*, 239 F.3d at 1234. In the patent-in-suit, dependent claim 3 states “[t]he device of claim 1 whereby said layer is capable of release of the at least one treating material by lysis of a chemical bond.” 22:57-59. “Lysis” refers to a more general process of breaking or decomposition of bonds, and “hydrolysis” refers to a particular type of “lysis” where the chemical bond breaking or decomposition is facilitated with water (i.e., the “hydro” specifically refers to breaking with water). *See Webster’s Third New Int’l Dictionary* 1351 (1993) (defining “lysis” as “decomposition <electrolysis> <hydrolysis> <pyrolysis>”). Given the relationship between the words “hydrolysis” and “lysis,” if the structure in independent claim 1 refers to chemical bonds and linkages that are hydrolyzable, then dependent claim 3 would be broader than claim 1 because it allows the treating material to be released by lysis of a chemical bond. Under the doctrine of claim differentiation, an independent claim should be given a broader scope than a dependent claim to avoid rendering the dependent claim redundant. *See Dow Chem. Co. v. United States*, 226 F.3d 1334, 1341-42 (Fed. Cir. 2000). Therefore, as in *Wegner*, the Court also concludes that the doctrine of claim differentiation supports the Court’s conclusion not to limit the chemical bonds and linkages to those hydrolyzable by water and/or enzymes.

The Court also rejects Defendants’ proposed directionality structure of “a layer that is substantially impermeable to the treating material and has the treating material affixed only to

the surface of the layer adjacent to the damaged tissue.” The Court believes that although the function does contain a directional component, the directionality structure proposed by Defendants is not necessary because the chemical bonds and linkages themselves provide the directionality. The phrase “material release means for release of at least one treating material in a directional manner” must be read in context with the next phrase that states “when said layer is placed adjacent to a damaged tissue.” Given that language, Defendants’ directionality structure, which essentially repeats that language and adds an “only” limitation, is redundant and thus not necessary. Therefore, the Court concludes that the structure for the means-plus-function is “chemical bonds and linkages.”

4. “the device being capable of substantially restricting the through passage of at least one type of macromolecule therethrough”

Claim Term/Phrase	Plaintiff’s Proposed Construction	Defendants’ Proposed Construction
<p>1. A flexible fixation device for implantation into human or animal tissue to promote healing of damaged tissue comprising:</p> <p>....</p> <p><i>the device being capable of substantially restricting the through passage of at least one type of macromolecule therethrough</i></p>	<p><i>The term “device” means:</i></p> <p>“at least the layer recited previously in the respective claims.”</p> <p><i>The phrase “capable of substantially restricting the through passage” means:</i></p> <p>“the device has the ability to substantially limit passage through the device.”</p> <p><i>The phrase “at least one type of macromolecule” means:</i></p> <p>“the at least one treating material recited previously in the respective claims.”</p>	<p><i>The term “device” means:</i></p> <p>“a single sheet of material.”</p> <p><i>The remainder of the phrase means:</i></p> <p>“the single sheet of material substantially restricts the through passage of at least one type of macromolecule and does not include a sheet of material on a stent that leaves uncovered mesh holes which allow macromolecules to freely move through them.”</p>

The Court has already construed the term “device” above. At oral argument, the parties agreed that the phrase “capable of substantially restricting the through passage” requires no construction. Hence, the only remaining disputes to decide are whether the Court will read in two specific limitations—one proposed by each side. Plaintiff argues the phrase “at least one type of macromolecule” should be limited to “the at least one treating material recited previously in the respective claims.” The Court refuses to read in this limitation. The Court also refuses to read in Defendants’ limitation that the device “does not include a sheet of material on a stent that

leaves uncovered mesh holes which allow macromolecules to freely move through them.” Instead, the Court concludes that the entire phrase “the device being capable of substantially restricting the through passage of at least one type of macromolecule therethrough” requires no construction.

This phrase also appears in claims 8 and 15. However, in claim 8 the language is “capable of restricting” instead of “capable of substantially restricting” as in claim 1. *Compare* 22:46-47; 23:32-33. The addition of “substantially” does not affect the Court’s construction because the parties again agree that the phrases should have the same construction regardless of the addition of the word “substantially.”

A. Parties’ Construction Arguments

Plaintiff argues the Court should construe the phrase “at least one type of macromolecule” as meaning “the at least one treating material recited previously in the respective claims.” Plaintiff supports this argument by citing to various references in the specification: release medicine can be “macromolecules” (6:34-40), the macromolecular containment means serves to “keep the medicine where it is most needed” (10:46-47), “[t]his example shows unidirectional delivery of medicine from the outer surface taking advantage of macromolecular containment means of the minimally-porous sheet” (11:30-33), and “[n]ote that both the macromolecules produced by the abnormal tissue and the treating material are contained within the interstices of the plaque by the macromolecular restraintment means of the invention” (11:42-47).

Defendants seek to add the limitation that the device “does not include a sheet of material on a stent that leaves uncovered mesh holes which allow macromolecules to freely move through

them.” Defendants’ argument is that this construction follows naturally if this Court accepts the construction that “device” means “sheet,” that is, if the device is a sheet that minimally restricts macromolecules then it cannot contain large uncovered mesh holes. Defendants argue the specification criticizes porous stents with uncovered mesh holes—so much so that it amounts to a disclaimer. Defendants also point to figures, including figure 8(e), that show the present invention completely wrapped around the stent with no mesh holes left uncovered.

Defendants argue the specification creates an intentional disclaimer of the claim scope. Defendants’ argument is best summed up by a quote from their brief:

A sheet on a stent that leaves uncovered openings or mesh holes that allow macromolecules to freely move through them is the antithesis of the ‘760 invention and would frustrate Saffran’s objective of blocking the migration of macromolecules away from the site of injury. As the specification states, “[t]he device itself **must be** substantially impermeable to macromolecules” 13:38-44 (emphasis added). This is “a **critical** aspect of the present invention” 14:8-10 (emphasis added). It is an “**exceedingly important** feature.” 20:49-51 (emphasis added). A sheet on a stent that leaves open mesh holes is not within the specification’s disclosure and cannot come within the proper scope of Saffran’s claims. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1367-68 (Fed. Cir. 2007) (specification’s description of “critical” feature found limiting).

(Dkt. No. 102 at 17 (emphasis in original).)

B. Analysis

The Court refuses to construe “at least one type of macromolecule” in accordance with Plaintiff’s construction as meaning “the at least one treating material recited previously in the respective claims.” Instead, the Court concludes that the phrase requires no construction. There is no dispute that the phrase “at least one type of macromolecule” could be the macromolecule produced by the treating material. However, the “at least one type of macromolecule” could also be a macromolecule produced by the abnormal tissue. Plaintiff even cites to the specification

where it discloses both the macromolecules produced by the abnormal tissue and the macromolecules produced by the treating material. 11:42-47 (“Note that both the macromolecules produced by the abnormal tissue and the treating material are contained within the interstices of the plaque by the macromolecular restraintment means of the invention.”). Therefore, the Court agrees with Defendants that “macromolecule” encompasses both types of macromolecules, and the Court will not limit it to “the at least one treating material recited previously in the respective claims” as requested by Plaintiff. It is presumed that Defendants agree that the phrase needs no construction since Defendants’ construction recites the language verbatim as “at least one type of macromolecule.” In any event, the Court concludes the phrase needs no construction.

The Court disagrees with Defendants’ disclaimer argument and thus refuses to read in Defendants’ limitation that the device “does not include a sheet of material on a stent that leaves uncovered mesh holes which allow macromolecules to freely move through them.” To find a disclaimer, the Court must find a “clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Liebel-Flarsheim*, 358 F.3d at 906 (internal quotes omitted). Additionally, “interpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.” *In re Cruciferous Sprout Litigation*, 301 F.3d at 1348 (internal quotes omitted). Neither the specification nor prosecution history shows a clear intention to limit the claim scope. Nowhere in the specification does the inventor disclaim a stent that leaves uncovered mesh holes. Defendants’ argument that it would be the “antithesis of the ‘760 invention” is not enough to find manifest exclusion or restriction. If anything, the inventor in the specification has

disclosed the possibility of spraying the invention on the stent. The specification states that the “spray stream . . . forms the invention when the spray hits a solid surface.” 12:64-65. While the only embodiment discussed in the specification in connection with the stent is a coat wrapped around the stent, presumably, if the inventor sprayed the invention on the stent, then as described above, the invention would be formed when the spray hit the solid surface on the stent. In that case there would be uncovered mesh holes that allow macromolecules to move freely through because the solid surfaces on a stent leave mesh holes. Thus, the Court refuses to incorporate Defendants’ limitation.

Other than an extraneous limitation proposed by each party, the parties have provided no construction or alternative constructions of the meaning of the phrase “the device being capable of substantially restricting the through passage of at least one type of macromolecule therethrough.” Further, much of the language in the phrase is not disputed by the parties because the parties are merely attempting to impose extraneous limitations through the interpretation of this phrase. Thus, since the Court rejects the parties’ extraneous limitations and there are no other apparent conflicts or proposed constructions by the parties, the Court concludes that the phrase “the device being capable of substantially restricting the through passage of at least one type of macromolecule therethrough” needs no construction. The Court has already construed the key terms within the phrase such as “macromolecule,” and given those constructions, the phrase as a whole would be understandable to a jury.

5. “lysis of a chemical bond”

Claim Term/Phrase	Plaintiff’s Proposed Construction	Defendants’ Proposed Construction
<i>“lysis of a chemical bond”</i> “3. The device of claim 1 whereby said layer is capable of a release of the at least one treating material by <i>lysis of a chemical bond</i> .”	“breaking a chemical bond”	“hydrolysis of a chemical bond”

The Court construes “lysis of a chemical bond” to be “breaking a chemical bond.” Plaintiff argues the term “lysis” as used in the claim would be understood by one of ordinary skill in the art to mean “breaking.” For support, Plaintiff cites a dictionary definition. *See Churchill’s Medical Dictionary* 1087 (1989) (defining “lysis” as “[a]ny form of dissolution, particularly the breaking of membrane-bound structures such as cells”). Defendants argue that the term “lysis” means “hydrolysis.” Defendants state that the only structure disclosed in the specification for the treating material is hydrolysis of a chemical bond, and Defendants argue that the inventor merely used “lysis” as shorthand for “hydrolysis” in claim 3.

The Court agrees with Plaintiff. Aside from claim 3, there is no mention of the word “lysis” in the intrinsic record. Therefore, the Court will consider extrinsic evidence to determine how one of ordinary skill in the art would understand the term “lysis.” Plaintiff’s dictionary definition supports a construction of the term “lysis” as “breaking.” The Court is unconvinced of Defendants’ argument that the inventor used “lysis” as shorthand for “hydrolysis” in claim 3. Rather, the inventor used the term “hydrolysis” many times in the specification, and the inventor never used “lysis” as shorthand for “hydrolysis” in the specification. *See, e.g.*, 10:14; 14:61; 15:2. This further shows the inventor knew how to use the word “hydrolysis,” so the fact that the

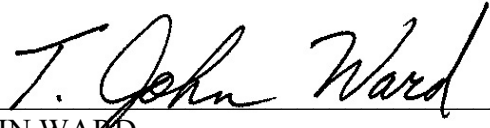
inventor did not use the word “hydrolysis” in claim 3 demonstrates the inventor did not mean “hydrolysis” in claim 3. Hence, the Court construes “lysis of a chemical bond” as “breaking a chemical bond.”

VI. CONCLUSION

The Court adopts the constructions set forth in this opinion for the disputed terms of the ‘760 patent. The parties are ordered that they may not refer, directly or indirectly, to each other’s claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the Court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.

It is so ORDERED.

SIGNED this 20th day of September, 2010.



T. JOHN WARD
UNITED STATES DISTRICT JUDGE